SAPIENS	SAMPLE COLLECTION MANUAL

1. AIM

This handbook has been prepared to set a certain standard for primary samples to be accepted to our laboratory. The book includes how to take the primary sample from the institutions and organizations we have agreements with, how to deliver it to our couriers, how much sample should be taken for which test, the characteristics of the transport containers in which the samples will be placed, filling out the Sample Shipment Form, sending delivery notes to the institutions that register online, laboratory analyzes presented to them, Information is available on identification, transportation, receipt, etc. of the primary sample.

2. SCOPE

3. ABBREVIATIONS

4. DEFINITIONS

Precious Sample: These are samples that require an intervention to be collected from the patient, such as CSF, amniotic fluid, bone marrow, cord blood, CVS material, skin biopsy, and samples from patients for whom it is difficult to obtain a new sample.

5. RESPONSIBILITIES

Sample Acceptance and Patient Registration Staff

Logistics Personnel

Laboratory Representatives of Contracted Institutions and Organizations, Blood Collection Center Managers

Laboratory manager

Laboratory Quality Management Representative

Current Status: The information contained in this manual is checked with the Laboratory Quality Management Representative and Laboratory Supervisor. In case of changes, the Sampling Manual is forwarded to laboratory employees via the common network by the Laboratory Quality Management Representative.

6. FLOW OF ACTIVITIES

6.1. Filling out the Sample Submission Form and Identifying the Samples
6.2. Factors Affecting the Analysis Result
6.3. The reference range
6.4. Working Program of Our Laboratory
6.5. Sample Collection and Preparation
6.6. Sample Storage Conditions
6.7. Sample Bag Preparation Rules
6.8. Critical / Panic Values
6.9. Sample Rejection / Acceptance Criteria
6.10. Receiving Additional Examination Requests and Conditional Sample Acceptance
6.11. Review of Sample Quantities
6.12. Preservation of Working Samples for a Specific Period
6.13. List of Services We Offer

6.14. Reporting Quality Control Results

6.1. FILLING OUT THE SAMPLE SUBMISSION FORM AND DEFINING THE SAMPLES

Correct identification of the sample is a critical step for a reliable laboratory result. It should not be forgotten that the most common source of laboratory errors is the preanalytical phase.

Our laboratory has prepared a Sample Submission Form to write down the required analyzes and necessary information for institutions that send samples without registering, other than institutions that register via the website. In this form;

Protocol Number,

Tube Name,

Desired Gene Names,

Requested Test/Panel,

DNA/RNA Concentration,

Number of Samples,

Type of sample,

Sent Institution,

Sample Admission Conditions

Name of the institution sending the form, e-mail address, phone number, date/time,

Sample Admission Conditions,

Sender Confirmation,

Receiver Approval

Additionally, the sample should be identified by writing the patient's name and surname in the Sample Submission Form on the sample material. Filling out the form completely and legibly is an important issue that the person in charge of the requesting institution should pay attention to.

Institutions that perform web registration are required to send the printout of the delivery note created after registration, along with samples.

*Each Sample Submission Form sent by the institutions is considered as an agreement and is processed.

6.2. FACTORS AFFECTING THE ANALYSIS RESULT

To obtain reliable and medically evaluable results, correct transportation and accurate analysis alone are not sufficient. The factors affecting the analysis results can be briefly summarized as follows.

Unchanged factors:

- Gender

- Race

- Extends

Changing factors:

- Drug use

- Having had a bone marrow transplant

- Pregnancy

-Endogenous factors

-Exogenous factors (Pharmacotherapy)

In case of lack of information about the patient and sample collection conditions, the laboratory can only evaluate a very limited part of these factors that may affect the accuracy of the analysis results. Therefore, reporting clinical information about the patient to the laboratory is extremely important so that comments and evaluations that can help the clinician can be made.

6.3. THE REFERENCE RANGE

The reference range specified for tests represents the group containing 95% of the values obtained from healthy individuals and provides a general basis for evaluating the test result. Depending on various factors, these values may vary from patient to patient. In cases where the analysis method changes, the reference range may also change depending on the method. The reference values in the report prepared for the patient are valid values.

6.4. WORKING PROGRAM OF OUR LABORATORY

All tests in the Sapiens Test Guide (except the tests sent to the application laboratory) are studied in our laboratory.

The working day and report dates of all tests performed in our laboratory are stated opposite the relevant test in the Sapiens Test Guide. General concepts related to these are summarized below;

Tests are run and reported within the periods specified in the Sapiens Test Guide.

6.5. SAMPLING AND PREPARATION PROCEDURE

I-BLOOD SAMPLES

Taking Blood Samples

Venous Blood Collection

During blood collection, the patient should be in a lying or sitting position and should rest in this position for at least 20 minutes.

The needle tip should be chosen as wide as possible.

The tourniquet should not remain tight on the arm for more than 30 seconds.

The vein should be squeezed with a maximum pressure of 60 mmHg.

The tourniquet should be removed after successful vein placement of the needle.

During blood collection with a syringe, strong aspiration of blood into the tube should be avoided.

Blood collection should be done in the following order:

For cytogenetic and molecular cytogenetic (FISH) tests, samples must be collected in heparin (green cap) tubes.

For molecular genetics and Microarray tests, samples must be collected in EDTA (purple cap) tubes.

* Particular attention should be paid to filling the vacuum tubes containing anticoagulants (citrate, EDTA, etc.) up to the marked line during blood collection.

*Immediately after drawing blood into tubes containing anticoagulant, the tube should be mixed carefully by gently inverting. Shaking should be strictly avoided!

Points to Consider:

It is very dangerous to centrifuge a blood sample that has been centrifuged once but whose serum separation has not been completed completely, in the same gel tube again! Since centrifuging a second time will cause cell damage, the cell contents will be released into the medium and may leak from the gel whose matrix is damaged and mix with the serum. Therefore, when complete and correct serum cannot be obtained, the serum on the gel should be transferred to Transport Tubes and centrifuged again.

Hemolyzed or cloudy serums are not suitable for many tests. A new sample should be taken.

Whole blood with EDTA

Tube: Vacuum plastic EDTA tube with purple cap

Taking an example:

Whole blood is collected up to the line in purple-capped EDTA tubes. To prevent clots from forming inside the tubes, the tube is mixed by gently inverting it 5-6 times as soon as blood is taken. Shaking should be strictly avoided.

During bleeding, special care should be taken to fill the blood up to the marked line.

Samples are stored in the refrigerator (2-8 °C).

Points to Consider:

If the blood is not taken completely up to the marked line on the tube or if a clot has formed in the tube, a new sample should be taken!

Whole Blood with Heparin

Tube: Vacuum Plastic lithium heparin tube with green cap.

Taking an example:

The blood sample is collected into green-capped tubes containing lithium heparin.

In order for the blood sample to mix with lithium heparin, the tubes should be inverted very slowly 5-6 times to ensure full contact of the blood with the anticoagulant.

Preservation of Blood Samples

After blood collection, the sample is kept at room temperature, away from direct sunlight, until the clotting process is completed. This duration is usually around 30 minutes. The presence of clotting accelerators in the blood collection tube shortens this time to 15 minutes. After this period, the serum must be separated from the clot by centrifugation.

TUBES RECOMMENDED BY OUR LABORATORY

TUBE	CAP COLOR	SIZE (MM)	VOLUME (ML)	AREA OF USE
EDTA TUBE	PURPLE	13 X 75	2-5	MOLECULAR GENETİC TESTS (DNA ISOLATİON)
HEPARIN TUBE (PLASTIC)	GREEN	13 X 75	2-5	CYTOGENETİC ANDFISH TESTS

II. TISSUE CULTURES

Materials such as abortion, amniotic fluid, chorionic villus, CVS are valuable samples.

Chorionic villus biopsy material (20-30 mg), skin biopsy (1-2 cm3), abortus material (1-2 cm3), (skin biopsy, placenta biopsy) samples should be sent to the laboratory in transport medium.

Amniotic fluid (approximately 20 ml) should be taken into a sterile syringe without a seal and sent in the same syringe without being transferred anywhere.

III. PARAFFIN BLOCK

Paraffin block samples are taken for molecular tests and FISH tests.

Paraffin block samples can be sent as a section of at least 2 slides with a thickness of 4-6 µm and fixed on the slide, or they can be sent as a paraffin block containing the tumor tissue.

6.6. SAMPLE STORAGE CONDITIONS

For a successful test and reliable results, it is extremely important to keep the samples taken from the patient under appropriate storage conditions. For this reason, the laboratory staff of the institution sending the sample are responsible for the preservation of the samples until the samples taken from the patients are delivered to SAPIENS Genetik ve Sağlık Hizmetleri A.Ş. Couriers and cargo.

Unless otherwise stated under the relevant test, samples should be stored within the temperature ranges specified in the SAPIENS Genetik ve Sağlık Hizmetleri A.Ş. Test Guide from collection until delivery to the SAPIENS Genetik ve Sağlık Hizmetleri A.Ş. Courier.

Our laboratory is not responsible for any result errors that may occur due to any errors made during the period until it is delivered to the SAPIENS Genetik ve Sağlık Hizmetleri A.Ş. courier.

6.7. SAMPLE BAG PREPARATION RULES

Bag and Material Specifications

SAPIENS Genetics and Health Services Inc. Sample Shipping Bag contains double-layer heat insulation material;

Our laboratory's transport bags are designed to ensure that your samples reach us in the most convenient way.

The outer structure of our bag has a hard structure that can protect the samples against external impacts by preserving the temperature inside. It ensures that the perforated sponge tubes of different sizes in our bag come upright and circulate the cold air in the bag.

The section inside the bag cover should be used for sending delivery note printouts and Sample Submission Forms.

After placing the bags in the bags, the covers of the bags should be closed. Since it is possible for bags that cannot be closed to be opened during transfer and the samples inside to be lost, it is mandatory to close the zippers of the bags.

Our laboratory is not responsible for sample losses in bags sent without their covers closed. Add the datalogger sent to you to the sample bag. Because this application is necessary to understand whether the sample comes under suitable temperature conditions or not.

Bag Layout.

Shipment samples are arranged appropriately in the tube holes in the “sponge rack”.

“Sample Submission Form” or “Delivery Note Printouts” related to the samples in the box are placed in the sections inside the bag cover.

NOTE: Use the samples sent to our laboratory and the materials sent to you by our laboratory (tubes, transport medium, etc.). Especially if the samples sent outside the screw cap spill during transportation, this causes the examinations to be delayed.

When accepting samples from our laboratory, care is taken to ensure that the bag belongs to our laboratory; otherwise, relevant institutions are warned. Please inform those responsible for replacement of damaged bags. Despite any risk of contamination, our laboratory and the official of the institution using the bag are responsible for the disinfection and sterilization of the bags.

6.8. CRITICAL / PANIC VALUES

Critical and panic values of the tests running in our laboratory have been prepared by our Laboratory Experts and by quoting from various current sources. When a panic critical value is detected as a result of any test, the relevant unit specialist calls the specialist and reports this value to the institution official (patient's doctor, Laboratory Supervisor or laboratory personnel, etc.).

6.9. SAMPLE ACCEPTANCE-REJECTION CRITERIA

Some of the issues that can be determined as rejection criteria for samples are as follows:

Samples sent in the wrong sample container/tube

Samples arriving at the laboratory more than 72 hours

Clotted blood samples

Sample tubes/sample containers are damaged

Samples sent with wrong indication (decided by discussing with the doctor)

Examples where patient identification information is missing

Samples where the Sample Submission Form and Informed Consent Form are missing or not fully filled out

frozen samples

Tissue samples such as abortion and CVS material have been placed in alcohol or formalin

Insufficient samples taken

OUR EXAMPLE REJECT-ACCEPT AREA

SAPIENS Genetik ve Sağlık Hizmetleri A.Ş. examines the suitability of all samples coming from institutions in the sample acceptance area, taking into account our Rejection - Acceptance Criteria. Our staff has received training on sample rejection and acceptance as part of their professional orientation training.

Rejected samples are kept in the refrigerator in this area.

Studies can be carried out on rejected samples upon written request of the institution and if the relevant expert deems it appropriate.

Samples that do not pass the acceptance process are taken to the rejection area and stored under appropriate conditions.

Information about rejected samples is conveyed to the relevant laboratories by the Patient Admission Personnel or the Sample Acceptance and Patient Registration Personnel during working hours.

6.10. RECEIVING ADDITIONAL EXAMINATION REQUESTS AND CONDITIONAL SAMPLE ACCEPTANCE

Additional Examination Requests

If requests such as adding a new test, canceling a test, repeating the sample studied, or requesting the sample back are made verbally by the institutions, a written statement (fax, e-mail, etc.) is requested from the institution. Requests that come to us with written approval from the customer are evaluated and necessary actions are taken.

The remaining samples from the tests are stored in appropriate temperature ranges (refrigerator, freezer, etc.) for at least 30 days to prevent the sample from losing its properties. Additional test requests received during this period are accepted.

Conditional admission

Working with Rejected Sample (Conditional Acceptance):

It works when samples rejected in our laboratory are requested to be studied by contracted institution personnel. If the relevant specialist gives approval, the Patient Admission Personnel or the Sample Acceptance and Patient Registration Personnel call the institution and inform them that the study will be carried out, and the samples approved for study are taken from the rejection area and processed by the relevant technician to be studied.

6.11. REVIEW OF SAMPLE QUANTITIES

The amount of sample required for each test performed in our laboratory is communicated to our customers through the SAPIENS Test Guide. Changes in the sample amounts required for tests are related to changes in working methods. When there is a change in working methods, institutions are informed through an external announcement.

6.12. STORAGE OF WORKED SAMPLES FOR A CERTAIN TIME

In some cases (customer request, verification test, etc.), samples that have been studied in our laboratory and whose results have been obtained need to be re-studied. In such cases, the samples to be reworked are kept in temperature ranges appropriate to the parameters of the test to be studied.

6.13. LIST OF THE SERVICES WE OFFER

According to the technical equipment adequacy in our laboratory and the agreements made with our customers;

Cytogenetic Tests

Molecular Genetic Tests

Tests are being studied under the following headings. The number of tests to be run under these headings can be increased or decreased depending on the conditions of the day. The test information we are working on is available up to date in the SAPIENS Test Guide delivered to you.

6.14. NOTIFICATION OF QUALITY CONTROL RESULTS

External quality control results of the test parameters studied in our laboratory are sent to institutions upon request. Institutions that want this are asked to contact our laboratory's quality unit and inform us in writing to the e-mail address they will receive from the quality unit, which tests and in which date range they want external quality control results. The quality unit sends the requested information to the institutions via e-mail.

7. RELATED DOCUMENTS

Sample Submission Form

Test Guide

Informed Consent Form

REVISION INFORMATION		
Revision date	**Revision Number**	**Revision Description**

PREPARER	APPROVED BY
Quality manager	